

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 58, 170, 171, 174, and 179

[Docket No. 99N-5556]

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Certifier R. LEDESMA

Food Additives: Food Contact Substance Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations regarding the premarket notification process for food contact substances (FCSs) established by the Food and Drug Administration Modernization Act (FDAMA) of 1997. The notification process is the primary method for authorizing new uses of food additives that are FCSs. FDA is codifying regulations that identify the circumstances under which a food additive petition (FAP) will be required to authorize the use of an FCS; specify the information required in a notification for an FCS; describe the administration of the notification process; and establish the procedure by which the agency may deem a notification to be no longer effective.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3083.

SUPPLEMENTARY INFORMATION:

cf00124

NFR-1

I. Background

In 1997, FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 348) to establish a premarket notification process as the primary method for authorizing new uses of food additives that are FCSs. In the proposed rule, published in the **Federal Register** of July 13, 2000 (65 FR 43269) (hereinafter referred to as the July 2000 proposal), FDA referred to a premarket notification for a food contact substance as a “PMN” and the process of premarket notification for such substances as the “PMN process.” This document refers to a premarket notification for a food contact substance as an “FCN” and to the process as the food contact notification (FCN) process. This change responds to a request from the comments (see section II.H of this document). A “food contact substance” is defined in section 409(h)(6) of the act as “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.” The FDAMA amendments and their legislative history make clear that the FCN process is to be the preferred process for authorizing new uses of food additives that are FCSs. Specifically, section 409(h)(3)(A) of the act states that the FCN process shall be utilized for authorizing the marketing of food additives that are FCSs except where the Secretary of Health and Human Services determines that the submission and review of a FAP is necessary to provide adequate assurance of safety, or where FDA and any manufacturer or supplier agree that a petition may be submitted. (See S. Rept. No. 105–43, 105th Cong., 1st sess. 46 (1997); H. Rept. 105–306, 105th Cong., 1st sess. 19 (1997).) FDA expects most new uses of FCSs that previously would have been regulated by issuance of a listing regulation in response to an FAP or would have been exempted from the requirement of a regulation under the threshold of regulation (TOR) process (21 CFR 170.39) will be the subject of FCNs.

The FCN program began operating on October 22, 1999, with the signing of FDA’s Fiscal Year 2000 budget. This budget met the requirements under section 409(h)(5) of the act for funding the FCN program. On October 25, 1999, FDA sent letters to trade associations and persons with

pending submissions (i.e., a food additive petition or a TOR exemption request) under active review by the agency to authorize use of an FCS. The letter stated that FDA expected to be ready to accept new FCNs on January 18, 2000, and requested that those persons with a pending submission for approval of an FCS under active review contact FDA prior to withdrawing such submission and converting it to an FCN. After October 25, 1999, FDA began working with the food packaging industry to convert these pending submissions under FDA review to FCNs.¹

In the **Federal Register** of November 12, 1999 (64 FR 61648), FDA published a notice announcing the availability of a draft guidance on the chemistry and toxicology information that should be included in an FCN. In the November 12, 1999, notice FDA requested comments on the guidance documents and on the information collection burden associated with the FCN program.

In addition, FDA published a direct final rule in the **Federal Register** of May 11, 2000 (65 FR 30352), that amended the agency's regulations on environmental impact considerations to permit manufacturers or suppliers to claim in FCNs the categorical exclusions currently applicable to FAPs and TOR exemption requests. The regulations in the May 11, 2000, direct final rule became effective on August 24, 2000.

Finally, in the July 2000 proposal (65 FR 43377), the agency proposed regulations to implement the FCN process and announced the availability of an administrative guidance document concerning the FCN process.

II. Comments on the Proposed Rule

The agency provided 75 days for comment on the proposed rule. FDA received comments from three trade associations representing the food packaging industry. In general, the comments supported the proposal. They also raised issues specific to the draft administrative guidance document announced with the proposed rule in the July 13, 2000, issue of the **Federal Register**

¹Between October 25, 1999, and December 31, 2000, FDA and industry converted 58 FAPs and 19 TOR submissions to FCNs. FDA currently lists those FCNs that have become effective on its Internet site at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

(65 FR 43377) and the draft chemistry and toxicology guidance documents announced in the **Federal Register** of November 12, 1999 (64 FR 61648). In accordance with FDA's good guidance practice (GGP) regulations (21 CFR 10.115), such comments have been addressed by modification of the final toxicology and chemistry guidance documents announced in the **Federal Register** of April 11, 2002 (67 FR 17703), and in FDA's revised administrative guidance document, the availability of which is published elsewhere in this issue of the **Federal Register**. Comments also requested that FDA clarify several specific issues in the proposal. These issues and FDA's responses follow.

(Comment 1) Two of the comments were concerned with the language in proposed § 170.104(b) describing FDA's initial review of an FCN submission. Proposed § 170.104(b) reads: "In order for the 120-day review period to begin FDA must accept that notification." The comments expressed the opinion that the language in proposed § 170.104(b) could be read to mean that the 120-day review period for the FCN does not begin until after FDA "accepts" the submission as an FCN. These comments referenced the language in section 409(h)(2)(A) of the act that states that a "* * * notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary * * *."

FDA agrees with these comments that the 120-day review period for the FCN runs from the date of receipt of a complete notification. The purpose of § 170.104(b) is to provide FDA with an opportunity to determine whether the submission is a complete notification and to ensure that FDA would not be required to review or object to an incomplete FCN. The following are examples of how FDA's initial review of FCN submissions has operated thus far and how FDA expects its initial review of FCNs to proceed in the future. FDA expects to determine whether an FCN is complete and reviewable within 30 days after receipt of a submission. If FDA finds that an FCN is complete and reviewable as received, then FDA will accept the FCN and the 120-day review period will continue to run from the date of receipt of the FCN. However, if FDA determines that, as submitted, an FCN is incomplete, the agency will request additional information

from the manufacturer or supplier. If the information is submitted before FDA issues a nonacceptance letter, FDA will accept the now complete FCN, and the 120-day review period begins on the date of receipt of the additional information. If the required additional information is not submitted, and the FCN is not withdrawn, FDA will issue a nonacceptance letter. Issuance of the nonacceptance letter will complete the review of the FCN submission.

In any case, the date of receipt of the complete FCN is the date of receipt for the purposes of section 409(h)(2) of the act. FDA is revising the language in § 170.104(b) to clarify that the 120-day review period begins on the date of receipt of a complete FCN and not on the date the FCN is accepted.

(Comment 2) All three comments requested that FDA clarify that the requirements in proposed § 170.101(c) regarding compliance with FDA's good laboratory practice regulations in part 58 (21 CFR part 58) do not apply to analytical testing (e.g., migration testing). The comments noted that analytical testing had not been previously required to comply with part 58. One comment requested that FDA make this clarification by explicitly referencing the definition of nonclinical laboratory studies in § 58.3.

FDA agrees that, historically, it has not applied its good laboratory practice regulations to analytical testing such as migration testing. Therefore, FDA is revising § 170.101(c) to explicitly reference the definition of nonclinical laboratory studies in § 58.3(d).

(Comment 3) All three comments requested that FDA make it clear that FCNs are required only for FCSs that are food additives. The comments referenced a statement in the preamble of the July 2000 proposal (65 FR 43269 at 43274) that reads as follows “* * * Under section 409(a) of the act, in the absence of an effective notification an FCS cannot be legally marketed.” One of the comments requested that FDA revise the referenced language to read as follows: “Under section 409(a) of the act, in the absence of an effective notification, an FCS that is a food additive cannot be legally marketed.”

FDA agrees with the comments that FCNs are required only for those FCSs that are food additives as defined by section 201(s) of the act (21 U.S.C. 321(s)). FDA intended the referenced statement to clarify that in cases where FDA objects to an FCN, the FCN cannot become effective. Because the language referred to was not in the codified portion of the proposed regulation, the agency is taking no further action in response to these comments.

FDA also believes, however, that the language suggested by one comment is misleading because it implies that FCSs are authorized only through the FCN process. Although the FCN process is the primary means for authorizing new uses of FCSs, some new uses of FCSs still will be authorized through the petition process in section 409(b) of the act.

(Comment 4) All three comments requested that FDA clarify the relationship of FDA Form 3480 to the recommendations in the agency's draft guidance documents for FCNs. The comment noted that adopting § 170.101(e), as proposed, would require that a completed and signed FDA Form 3480 be included in an FCN. FDA Form 3480 requires that manufacturers or suppliers list summary toxicology information on the FCS and its constituents. In addition, the comments noted, the draft guidance on toxicology information in an FCN advises that notifiers (i.e., manufacturers and suppliers) should provide a comprehensive toxicological profile for the FCS and its constituents. The comments expressed uncertainty about the level of detail required in FDA Form 3480. The comments noted that the draft toxicology guidance document appeared to request that some of the same information be included in both the comprehensive toxicology profile and the safety narrative, as is required in FDA Form 3480. Thus, a notifier might have to list the same information in two sections of a notification.

FDA has revised FDA Form 3480 (Ref. 1) to minimize duplication of effort in developing the toxicology package for FCNs. FDA also has revised its guidance documents to assist manufacturers and suppliers in completing FDA Form 3480. Published elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of administrative, chemistry, and toxicology guidance documents.

(Comment 5) One comment requested that FDA make mandatory the issuance by the agency of a final letter for FCNs that become effective. The comment argued that the listing of notifications in FDA's inventory of effective notifications on the agency's Internet site may not be adequate to inform interested persons regarding the status of an FCN. In addition, the comment contended that listing of notifications on FDA's Internet site may not be completed in a timely manner.

FDA disagrees with this comment. The statute does not require FDA to issue a letter at the conclusion of the review of an FCN. Indeed, no action is required by FDA for an FCN to become effective. FDA believes that issuance of final letters for effective FCNs has some value, but FDA is concerned that the issuance of such letters may consume limited resources that are necessary to complete a timely review of FCNs. Therefore, FDA is denying the request to require the agency to issue a final letter for effective notifications. However, as noted above, FDA has been reviewing FCNs since the program began operating and, since that time, FDA has consistently issued final letters and listed effective notifications on its Internet site in a timely manner. Accordingly, FDA expects to continue to issue final letters as long as the resources necessary to do so do not prevent timely review of FCNs.

(Comment 6) One comment requested that FDA provide an opportunity for a company to notify the agency of any change in name or corporate structure subsequent to its filing of an FCN. The comment also requested that FDA establish a procedure whereby FDA would change the name of the manufacturer in the listing of the FCN on FDA's Internet site and reissue the final letter for the FCN with the new company's name.

The agency agrees in part with this comment. Under § 170.100(d), manufacturers or suppliers are required to keep on file with FDA an address at which FDA may contact the manufacturer or supplier regarding the notification. FDA already had one experience with the sale of the manufacturing unit of a notified FCS from one company to another. In that case, the original manufacturer verified the sale and FDA changed the name of the manufacturer in the listing for the FCN on the agency's Internet site. FDA did not, however, reissue the final letter. FDA believes

that reissuing final letters would be an ineffective use of its limited resources. Therefore, FDA will not reissue an updated final letter when the manufacturer or supplier of the FCN changes. FDA has included guidance on the above procedure in “Preparation of Premarket Notifications for Food Contact Substances: Administrative Recommendations,” the availability of which is announced elsewhere in this issue of the **Federal Register**.

FDA also is revising the language in all the regulations to replace the word “notifier” with the words “manufacturer or supplier.” FDA believes “manufacturer or supplier” is more appropriate because it is the term used in section 409(h) of the act.

(Comment 7) One comment requested that FDA clarify its position on the issue of transferability of FCNs. Specifically, the comment requests that FDA establish regulations to permit a manufacturer identified in an effective FCN to transfer the rights granted under an effective notification. The comment contended that licensing the manufacture of an FCS would maintain the safety of the FCS because it would continue to be manufactured in the manner reviewed by the agency.

At the time of the proposal, FDA did not contemplate regulations to permit a subsequent manufacturer other than the manufacturer identified in the FCN to produce and market the FCS under that FCN and did not discuss such regulations in the proposed rule. Thus, FDA believes that the issues raised in this comment are outside the scope of the proposal. Currently, FDA requires any subsequent manufacturer who wishes to market an FCS for a use that is the subject of an already effective FCN to submit a notification to FDA. In addition, the manufacturer identified in an effective FCN may authorize other manufacturers to reference information contained in the effective FCN. Thus, other manufacturers may have to provide only limited additional information in subsequent FCNs but they must notify FDA separately and wait 120 days for their FCN to become effective. However, FDA is interested in hearing the views of other interested parties on this issue. Therefore, elsewhere in this issue of the **Federal Register**, FDA is publishing an

advanced notice of proposed rulemaking requesting comments on the issue of transferability of FCNs.

(Comment 8) All three comments requested FDA to replace the abbreviation “PMN” with “FCN” to represent a premarket notification for a food contact substance (also called a Food Contact Notification). The comments argued that this change will avoid confusing a premarket notification for a food contact substance with a “PMN” submitted to the U.S. Environmental Protection Agency (EPA).

FDA already made this change in the operation of the FCN program, throughout this document, and where appropriate in the codified regulations. FDA also made other nonsubstantive editorial changes in the regulations.

(Comment 9) In § 170.100(a)(2), FDA is replacing the word “should” with “must.” FDA is making this change to be consistent with the description of the provision in the proposed rule. In the preamble of the proposed rule, the agency stated that it would permit a manufacturer or supplier to incorporate by reference information in FDA’s files where the submitter of the information has given the notifier permission to reference the information (65 FR 43269 at 43271). Requiring the manufacturer or supplier to establish that it has permission to incorporate certain information by reference also is consistent with standard FDA practice on incorporation by reference. (See 21 CFR 171.1(f); 21 CFR 314.420(d); 21 CFR 571.1(f); 21 CFR 814.20(c).)

III. Summary and Conclusions

The comments received in response to the July 2000 proposal requested changes to the proposed language in §§ 170.101(c) and 170.104(b). In addition, FDA is revising certain language throughout the proposed regulations. Because no comments were received relating to the remaining regulations included in the July 2000 proposal, FDA is finalizing those regulations as proposed with only minor editorial changes. Listed below are the revisions that are being incorporated into this final rule, based on the comments received in response to the proposal:

1. FDA is replacing the term “notifier” with the term “manufacturer or supplier” throughout the regulations to correspond with the language in section 409(h) of the act.

2. FDA is revising the language in § 170.101(c) to reference the definition of nonclinical laboratory studies in § 58.3(d) to clarify that 170.101(c) does not apply to analytical testing to determine the functionality or to determine physical or chemical characteristics of the test article.

3. FDA is revising the language in § 170.104(b) to clarify that the 120-day review period for an FCN begins on the date FDA receives the complete FCN. Thus, where FDA receives an incomplete FCN, the 120-day review period begins when FDA receives the missing information.

4. FDA is replacing the acronym “PMN” with “FCN” to refer to a premarket notification for a food contact substance (also known as a Food Contact Notification). FDA is using the acronym FCN throughout this document and in the codified regulations.

5. In § 170.100(a)(2) FDA is replacing the word “should” with “must.”

IV. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Contact Substances Notification System.

Description: Section 409(h) of the act establishes a premarket notification process for FCSs. Section 409(h)(6) of the act defines a “food contact substance” as “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.” Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of FCSs except where FDA determines that the submission and premarket review of an FAP under section

409(b) of the act is necessary to provide adequate assurance of safety or where FDA and the manufacturer or supplier agree that a petition should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the FCS and the basis for the manufacturer's or supplier's determination that the FCS is safe under the intended conditions of use. Because section 409(h)(1) of the act references the general safety standard for food additives, the data in an FCN should be comparable to the data in an FAP. FDA is issuing regulations necessary to implement the FCN program that will largely replace the FAP process for those food additives that are FCSs.

Also, FDA is requiring that an FCN include FDA Form 3480 entitled "Notification for New Use of a Food Contact Substance" (Ref. 1) and is requiring that a notification for a food contact substance formulation (NFCSF) include FDA Form 3479 entitled "Notification for a Food Contact Substance Formulation" (Ref. 2). These forms will serve to summarize pertinent information in the notification. FDA made Form 3480 available for public comment in the November 12, 1999 (64 FR 61648 at 61649), notice and Form 3479 available for public comment in the July 2000 proposal (65 FR 43269 at 43277). FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the FCS. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents: Manufacturers of food contact substances.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106 ²	FDA 3479	200	4	800	2	1,600
170.101 ^{3,7}	FDA 3480	200	1	200	25	5,000
170.101 ^{4,7}	FDA 3480	55	2	110	120	13,200
170.101 ^{5,7}	FDA 3480	45	2	90	150	13,500
107.101 ^{6,7}	FDA 3480	16	1	16	150	2,400
Total						35,700

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Notifications for a food contact substance formulation. These notifications require only FDA Form 3479 ("Notification for a Food Contact Substance Formulation") to be filled out and documentation attached.

³ Duplicate notifications for uses of FCSs.

⁴ Notifications for uses that currently would be the subject of exemptions under 21 CFR 170.39 or very simple FAPs.

⁵ Notifications for uses that currently would be the subject of moderately complex FAPs.

⁶ Notifications for uses that currently would be the subject of more complex FAPs.

⁷ These notifications require the submission of FDA Form 3480 ("Notification for New Use of a Food Contact Substance").

The above estimate is based on the types of submissions that FDA currently receives for food contact substances in the TOR and the FAP processes and the following assumptions and information:

- FDA estimates that the likely increase in FCNs over the number of FAPs and TOR requests will be approximately four times the highest recent annual influx of these submissions (50 and 54, respectively). This factor is based on an analysis of the number of companies producing various types of FCSs and the types of FCSs for which FAPs and TORs most commonly are submitted to FDA.

- Based on input from industry sources, FDA estimates that the agency will receive approximately 800 notifications annually for food contact substance formulations.

- FDA also has included 200 expected duplicate submissions in the second lowest tier. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out FDA Form 3480, verifying that a previous notification is effective, and preparing necessary documentation.

- Based on the amount of data typically submitted in FAPs and TOR requests, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information.

- FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

In the July 2000 proposal (65 FR 43269 at 43276), the agency requested comments on the proposed collection of information. On October 3, 2000, OMB filed comment on the information collection provisions, assigning OMB control number 0910-0447. OMB's comments stated that, "FDA shall evaluate the contents of this collection in light of any comments received regarding the information collection requirements contained in the rule. In addition, FDA shall address any issues related to reducing duplication between FDA and EPA related to this collection."

FDA received no comments on the information collection requirements in the proposed rule. FDA continues to work with EPA and the U.S. Department of Agriculture (USDA) to eliminate areas of duplicative data collection and evaluation. Within the past 2 years USDA has eliminated its separate approval process for components of food contact materials that duplicated FDA's process. In addition, the Food Quality Protection Act of 1996 gave sole jurisdiction to EPA for certain substances formerly regulated by FDA as food additives and by EPA as pesticide chemicals. Currently, there is no significant duplication of data collection and evaluation for food contact substances among Federal agencies with jurisdiction. In addition, to avoid unnecessary duplication for individual submissions, existing data will be used whenever possible by FDA in evaluating notifications for food contact substances.

FDA submitted the information collection provisions of this final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Analysis of Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation also is considered

a significant regulatory action if it raises novel legal or policy issues. OMB determined that this final rule is a significant regulatory action as defined by Executive Order 12866. Accordingly, OMB has reviewed this final rule and has approved its publication in the **Federal Register**.

There were no comments that pertained directly or indirectly to the preliminary regulatory impact analysis (PRIA) so FDA has made no change in the evaluation of the regulation for the final regulatory impact analysis. The rulemaking was necessary to implement the FCN process established by FDAMA. The notification process largely will replace the FAP process for FCSs. The FCN process requires FDA to object within 120 days to the notification of an FCS manufacturer or supplier that it intends to market a particular food contact substance for a specific use, or the substance may be marketed legally on the 121st day without issuance of a regulation.

FDA estimates that the social benefits of the change in regime will be from new product innovation. The agency estimates that four times the current annual number of petitions and threshold of regulation exemptions will be introduced into the market, for a total of 416. The social costs from the change in regimes are the costs to submit duplicate notifications. The agency estimates that 50 percent of the total will be duplicates for a total social cost of \$26,387,500. For a full explanation of the estimated costs and benefits of this final rule, see the preliminary regulatory impact assessment published in the July 2000 proposal (65 FR 43269 at 43277), which is incorporated by reference.

B. Final Regulatory Flexibility Analysis

1. Introduction

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612.) If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

There were no comments that pertained directly or indirectly to the initial regulatory flexibility analysis so FDA made no change in the evaluation of the regulation for the final regulatory flexibility analysis. The final rule could affect small businesses because new costs will be imposed that did not exist before the change in regimes. A small firm that wants to introduce a new FCS will have to produce more documentation after the final rule than before. However, because the final rule reduces the uncertainty about the period of evaluation of new uses of substances, firms that rely heavily on the authorization of a unique use of a substance stand to benefit the most. Because new small businesses may rely on innovation that requires new use authorization, they are more likely to benefit the most from the final rule. However, they also may incur proportionately greater costs than if they would have relied on rival firms to incur the authorization costs.

3. Regulatory Relief

Because some small firms are expected to be adversely affected by the final rule, options for regulatory relief, such as a small business exemption, were addressed in the proposed rule. The benefit of this option is that small businesses would not incur an additional cost. The drawback is that small firms could copy and distribute themselves the substances being reviewed in response to the marketing submission of a competitor, thus, creating disincentives for new substance development by rival firms.

4. Description of Recordkeeping and Reporting

There are no additional recordkeeping requirements for the final rule.

5. Summary

FDA estimates that there will be no net costs to small businesses because of this final rule. If small business entities determine that the costs of notification outweigh the benefits, the small business entities could rely on existing authorized FCSs.

C. Unfunded Mandates

Section 1531(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), defines a significant rule as a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any one year. FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995.

VI. Environmental Impact

The agency previously reviewed the potential environmental effects of this final rule as announced in the July 2000 proposal (65 FR 43269). The agency concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Form No. 3480 “Notification for a New Use of A Food Contact Substance,” Rev. 9/01.
2. FDA Form No. 3479 “Notification for a Food Contact Substance Formulation,” Rev. 5/00.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 58

Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

21 CFR Part 174

Food additives, Food packaging.

21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20, 58, 170, 171, 174, and 179 are amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.100 is amended by adding paragraph (c)(41) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * *

(c) * * *

(41) Premarket notifications for food contact substances, in § 170.102 of this chapter.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

3. The authority citation for 21 CFR part 58 continues to read as follows:

Authority: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

4. Section 58.3 is amended by adding paragraph (e)(23) to read as follows:

§ 58.3 Definitions.

* * * *

(e) * * *

(23) A premarket notification for a food contact substance, described in part 170, subpart D, of this chapter.

* * * *

PART 170—FOOD ADDITIVES

5. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

6. Section 170.3 is amended by revising paragraph (e)(2) and by adding paragraph (e)(3) to read as follows:

§ 170.3 Definitions.

* * * *

(e)(1) * * *

(2) *Uses of food additives not requiring a listing regulation.* Use of a substance in a food contact article (e.g., food-packaging or food-processing equipment) whereby the substance migrates, or may reasonably be expected to migrate, into food at such levels that the use has been exempted

from regulation as a food additive under § 170.39, and food contact substances used in accordance with a notification submitted under section 409(h) of the act that is effective.

(3) A *food contact substance* is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

* * * * *

7. Subpart D, consisting of §§ 170.100 through 170.106, is added to part 170 to read as follows:

Subpart D—Premarket Notifications

Sec.

170.100 Submission of a premarket notification for a food contact substance (FCN) to the Food and Drug Administration (FDA).

170.101 Information in a premarket notification for a food contact substance (FCN).

170.102 Confidentiality of information in a premarket notification for a food contact substance (FCN).

170.103 Withdrawal without prejudice of a premarket notification for a food contact substance (FCN).

170.104 Action on a premarket notification for a food contact substance (FCN).

170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

170.106 Notification for a food contact substance formulation (NFCSF).

Subpart D—Premarket Notifications

§ 170.100 Submission of a premarket notification for a food contact substance (FCN) to the Food and Drug Administration (FDA).

(a) An FCN is effective for the food contact substance manufactured or prepared by the manufacturer or supplier identified in the FCN submission. If another manufacturer or supplier

wishes to market the same food contact substance for the same use, that manufacturer or supplier must also submit an FCN to FDA.

(1) An FCN must contain all of the information described in § 170.101.

(2) An FCN may incorporate by reference any information in FDA's files provided that the manufacturer or supplier is authorized to reference the information. The FCN must include information establishing that the manufacturer or supplier is authorized to reference information in FDA's files.

(3) Any material submitted in or referenced by an FCN that is in a foreign language must be accompanied by an English translation verified to be complete and accurate.

(b) FDA may choose not to accept an FCN for either of the following:

(1) A use of a food contact substance that is the subject of a regulation in parts 173 through 189 of this chapter; or

(2) A use of a food contact substance that is the subject of an exemption under the threshold of regulation process described in § 170.39.

(c) A petition must be submitted under § 171.1 of this chapter to authorize the safe use of a food contact substance in either of the following circumstances, unless FDA agrees to accept an FCN for the proposed use.

(1) The use of the food contact substance increases the cumulative dietary concentration to a certain level. For a substance that is a biocide (e.g., it is intended to exert microbial toxicity), this level is equal to or greater than 200 parts per billion in the daily diet (0.6 milligram (mg)/person/day). For a substance that is not a biocide, this level is equal to or greater than 1 part per million in the daily diet (3 mg/person/day); or

(2) There exists a bioassay on the food contact substance, FDA has not reviewed the bioassay, and the bioassay is not clearly negative for carcinogenic effects.

(d) A manufacturer or supplier for which a notification is effective must keep a current address on file with FDA.

(1) The current address may be either the manufacturer's (or supplier's) address or the address of the manufacturer's (or supplier's) agent.

(2) FDA will deliver correspondence to the manufacturer's or supplier's current address.

§ 170.101 Information in a premarket notification for a food contact substance (FCN).

An FCN must contain the following:

(a) A comprehensive discussion of the basis for the manufacturer's or supplier's determination that the use of the food contact substance is safe. This discussion must:

(1) Discuss all information and data submitted in the notification; and

(2) Address any information and data that may appear to be inconsistent with the determination that the proposed use of the food contact substance is safe.

(b) All data and other information that form the basis of the determination that the food contact substance is safe under the intended conditions of use. Data must include primary biological data and chemical data.

(c) A good laboratory practice statement for each nonclinical laboratory study, as defined under § 58.3(d) of this chapter, that is submitted as part of the FCN, in the form of either:

(1) A signed statement that the study was conducted in compliance with the good laboratory practice regulations under part 58 of this chapter; or

(2) A brief signed statement listing the reason(s) that the study was not conducted in compliance with part 58 of this chapter.

(3) Data from any study conducted after 1978 but not conducted in compliance with part 58 of this chapter must be validated by an independent third party prior to submission to the Food and Drug Administration (FDA), and the report and signed certification of the validating party must be submitted as part of the notification.

(d) Information to address FDA's responsibility under the National Environmental Policy Act, in the form of either:

(1) A claim of categorical exclusion under § 25.30 or § 25.32 of this chapter; or

(2) An environmental assessment complying with § 25.40 of this chapter.

(e) A completed and signed FDA Form No. 3480.

§ 170.102 Confidentiality of information in a premarket notification for a food contact substance (FCN).

(a) During the 120-day period of the Food and Drug Administration (FDA) review of an FCN, FDA will not disclose publicly any information in that FCN.

(b) FDA will not disclose publicly the information in an FCN that is withdrawn prior to the completion of FDA's review.

(c) Once FDA completes its review of an FCN, the agency will make its conclusion about the FCN publicly available. For example, if FDA objects to a notification 90 days after the date of receipt, the agency would make available its objection at that time.

(d) By submitting an FCN to FDA, the manufacturer or supplier waives any claim to confidentiality of the information required to adequately describe the food contact substance and the intended conditions of use that are the subject of that FCN.

(e) The following data and information in an FCN are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by FDA, except that no data or information are available for public disclosure if the FCN is withdrawn under § 170.103.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food contact substance for establishing identity, stability, purity, potency, performance, and usefulness.

(2) A protocol for a test or study, unless it is exempt from disclosure under § 20.61 of this chapter.

(3) A list of all ingredients contained in a food contact substance, excluding information that is exempt from disclosure under § 20.61 of this chapter. Where applicable, an ingredient list will be identified as incomplete.

(4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is exempt from disclosure under § 20.61 of this chapter.

(5) All correspondence and written summaries of oral discussions relating to the notification, except information that is exempt for disclosure under § 20.61 of this chapter.

(6) All other information not subject to an exemption from disclosure under subpart D of part 20 of this chapter.

§ 170.103 Withdrawal without prejudice of a premarket notification for a food contact substance (FCN).

A manufacturer or supplier may withdraw an FCN without prejudice to a future submission to the Food and Drug Administration (FDA) if FDA has not completed review of the FCN. For the purpose of this section, FDA's review is completed when FDA has allowed 120 days to pass without objecting to the FCN or FDA has issued an objection letter.

§ 170.104 Action on a premarket notification for a food contact substance (FCN).

(a) If the Food and Drug Administration (FDA) does not object to an FCN within the 120-day period for FDA review, the FCN becomes effective.

(b) If an FCN is complete when received, the 120-day review period begins on the date FDA receives the FCN.

(1) If any element required under § 170.101 is missing from an FCN, then FDA will not accept that FCN and FDA will send an FCN nonacceptance letter to the manufacturer or supplier. If the manufacturer or supplier submits the missing information before FDA sends an FCN nonacceptance letter, the 120-day review period begins on the date of receipt of the missing information.

(2) If FDA accepts an FCN, then FDA will acknowledge in writing its receipt of that FCN.

(c) Objection to an FCN:

(1) If FDA objects to an FCN, then FDA will send an FCN objection letter. The date of the letter will be the date of FDA's objection for purposes of section 409(h)(2)(A) of the act.

(2) If FDA objects to an FCN within the 120-day period for FDA review, the FCN will not become effective.

(3) FDA may object to an FCN if any part of FDA's 120-day review occurs during a period when this program is not funded as required in section 409(h)(5) of the act.

(d) If FDA and a manufacturer or supplier agree that the notifier may submit a food additive petition proposing the approval of the food contact substance for the use in the manufacturer's or supplier's FCN, FDA will consider that FCN to be withdrawn by the manufacturer or supplier on the date the petition is received by FDA.

§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

(a) If data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of the food contact substance is no longer safe, FDA may determine that the authorizing FCN is no longer effective.

(b) If FDA determines that an FCN is no longer effective, FDA will inform the manufacturer or supplier in writing of the basis for that determination. FDA will give the manufacturer or supplier an opportunity to show why the FCN should continue to be effective and will specify the time that the manufacturer or supplier will have to respond.

(c) If the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the FCN is no longer effective. FDA will publish this notice in the **Federal Register**, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display

and that copies are available upon request. The date that the notice publishes in the **Federal Register** is the date on which the notification is no longer effective.

(d) FDA's determination that an FCN is no longer effective is final agency action subject to judicial review.

§ 170.106 Notification for a food contact substance formulation (NFCSF).

(a) In order for the Food and Drug Administration (FDA) to accept an NFCSF, any food additive that is a component of the formulation must be authorized for its intended use in that NFCSF.

(b) FDA may publish a notice in the **Federal Register** stating that the agency has insufficient resources to review NFCSFs. From the date that this notice publishes in the **Federal Register**, FDA will no longer accept NFCSFs.

(c) An NFCSF must contain the following:

(1) A completed and signed FDA Form No. 3479; and

(2) Any additional documentation required to establish that each component of the formulation already may be marketed legally for its intended use.

PART 171—FOOD ADDITIVE PETITIONS

8. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

9. Section 171.1 is amended by revising paragraph (i)(1) to read as follows:

§ 171.1 Petitions.

* * * * *

(i)(1)(i) Within 15 days after receipt, the Food and Drug Administration will notify the petitioner of the acceptance or nonacceptance of a petition, and if not accepted, the reasons therefor. If accepted, the petitioner will be sent a letter stating this and the date of the letter shall become

the date of filing for the purposes of section 409(b)(5) of the act. In cases in which the Food and Drug Administration agrees that a premarket notification for a food contact substance (Food Contact Notification (FCN)) submitted under section 409(h) of the act may be converted to a petition, the withdrawal date for the FCN will be deemed the date of receipt for the petition.

(ii) If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, the petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified.

(iii) Notwithstanding paragraph (i)(1)(ii) of this section, the petition shall not be filed if the Food and Drug Administration determines that the use identified in the petition should be the subject of an FCN under section 409(h) of the act rather than a petition.

* * * * *

10. Section 171.7 is amended by adding paragraph (c) to read as follows:

§ 171.7 Withdrawal of petition without prejudice.

* * * * *

(c) Any petitioner who has a food additive petition pending before the agency and who subsequently submits a premarket notification for a food contact substance (FCN) for a use or uses described in such petition shall be deemed to have withdrawn the petition for such use or uses without prejudice to a future filing on the date the FCN is received by the Food and Drug Administration.

PART 174—INDIRECT FOOD ADDITIVES: GENERAL

11. The authority citation for 21 CFR part 174 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

12. Section 174.5 is amended by adding paragraph (d)(5) to read as follows:

§ 174.5 General provisions applicable to indirect food additives.

* * * * *

(d) * * *

(5) Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

13. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

14. Section 179.25 is amended by revising paragraph (c) to read as follows:

§ 179.25 General provisions for food irradiation.

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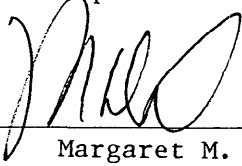
(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged food shall be in compliance with § 179.45, shall be the subject of an exemption for such use under § 170.39 of this chapter, or shall be the subject of an effective premarket notification for a food contact substance for such use submitted under § 170.100 of this chapter.

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Dated: 9/28/01

September 28, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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